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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Customer No.	49437
Group	1656
Inventor	Ihlenfeldt et al.
Confirmation No.:	5091
Application No.:	10/680,635
Invention:	A RECOMBINANT KINASE FROM INSECT CELLS FOR THE SYNTHESIS OF NUCLEOSIDE MONOPHOSPHATES
Filed:	October 7, 2003
Attorney Docket:	6398-201320
Examiner:	Alexander Kim

DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. HANS-GEORG IHLENFELDT

Mail Stop RCE
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22213-1450

I, Dr. Hans-Georg Ihlenfeldt, declare as follows:

1. I am currently Director of Manufacturing within Roche Applied Sciences at Roche Diagnostics GmbH in D-82372 Penzberg, Germany. I received a Doctorate of Philosophy degree (Ph.D.) from the University of Tubingen, Germany in July 1995. My research has centered on biotechnological aspects such as peptide chemistry.

immunology and enzymatic synthesis. I have authored two, as well as co-authored more than five peer-reviewed journal articles in the area of my research interests.

2. I am one of the named co-inventors of the captioned application. I am familiar with the research that was conducted to reduce the claimed invention to practice. I have read and understand the specification of the captioned application and the pending claims in the application. I understand that the nucleic acid sequence of the recombinant *Drosophila melanogaster* kinase as depicted in Fig. 5 and in SEQ ID NO: 1 has the designation of "R" at position 308. I hereby state that the designation of "R" at position 308, in both the sequences represented in Fig. 5 and as SEQ ID NO: 1 in US patent application no 10/680,635 represents a drafting error in the preparation of the patent application. This same error is present in the *Drosophila melanogaster* kinase sequence depicted as Figure 5/SEQ ID NO: 1 in the original priority application, DE 198 46 838.5 (filed on October 12, 1998). In each instance the sequence references as the *D. melanogaster* kinase gene should have designated a "T" at position 308 rather than an "R".

3. In further support that the sequence represented in Fig. 5 and as SEQ ID NO: 1 in US patent application no. 10/680,635 represents a clerical error, I submit the following:

a) The specification describes the cloning and the sequencing of the *D. melanogaster* kinase gene. The sequence obtained using the method disclosed in the application (as specifically detailed on page 5 lines 10 through page 7, line 19) is the sequence of Figure 5 and SEQ ID NO: 1 as provided in the original filed US application no. 10/680,635, but having a "T" at position 308 instead of an "R".

b) The sequence obtained using the method disclosed in US application no. 10/680,635 (as specifically detailed on page 5 lines 10-20) represents the native sequence of the *D. melanogaster* kinase gene.

c) As indicated by Munch-Petersen et al., Journal of Biological Chemistry, Vol. 273, p. 3926-3931 (February, 1999), the genome of *D.*

melanogaster contains only one major deoxyribonuclease kinase gene. Furthermore, in a later publication, Johansson et al., Journal of Biological Chemistry, Vol. 274, p. 23814-23819 (August, 1999) provides the sequence of that gene and indicate that the nucleotide sequence of **the** *D. melanogaster* kinase gene comprises a "T" at position 308.

d) The presence of any nucleotide other than "T" at position 308 will result in a change in the amino acid sequence of the encoded gene product. This is because the nucleotide positions 307-309 represent the codon "ATG" of the *D. melanogaster* kinase gene, and ATG is the only codon that encodes for methoinine. Therefore, the designation of an "R" at position 308 is an obvious error because the presence of a "G" or an "A" at that position would produce an amino acid substitution relative to the native the *D. melanogaster* kinase.

e) As stated on page 9 of the specification of US application no. 10/680,635, Figure 5 was intended to represent "the DNA sequence of the clone". Thus the application is directed to cloning the gene in its native state, and was not intended to claim a modified version of the native sequence.

At the time the application was filed applicants knew the entire nucleotide and amino acid sequence of the native *Drosophila melanogaster* kinase gene, and knew that the nucleotide at position 308 was a "T". However, the sequence was mistakenly listed as including an "R" at position 308 instead of a "T". This mistake was made with no deceptive intent on the part of applicants. Applicants did not notice this obvious error in the sequence until the Examiner noted the error in his final Office Action of May 15, 2007.

3. I hereby state that the inventors were in full possession of the claimed invention at the time the application was filed, including the complete sequence of the *Drosophila melanogaster* kinase gene as depicted in Fig. 5, with a "T" at position 308 instead of an "R".

Appl. No 10/680,635
Declaration of Hans-Georg Ihlenfeldt

All statements herein made of my own knowledge are true, and all statements herein made on information and belief are believed to be true; these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 25th Feb 2009

By: Hans-Georg Ihlenfeldt, Ph.D.